K103295

FEB - 1 2012

510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)

Manufacturer & Submitter: Phamatech Inc.
10151 Barnes Canyon Road
San Diego, California 92121, USA

Contact: Carl A. Mongiovi
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Date Prepared 1/15/2011

Proprietary Name: QuickScreen Drug Screening Test System

Common Name: Drug of Abuse Rapid Test System

Description: Immunoassay for the qualitative detection, Amphetamine, THC, Cocaine, PCP, Barbiturates, Benzodiazepines, Methadone, Oxycodone, Opiates and Methamphetamine in urine

Classification Names:

The applicant test system regulatory classification is Class II, Classification Panel is Clinical Toxicology (91). Regulatory information applicable to this test system is provided below:

CFR section		Product Code
862.3100	Amphetamine test system	DKZ
862.3150	Barbiturate test system	DIS
862.3170	Benzodiazepine test system	JXM
862.3250	Cocaine/cocaine metabolite test system	DIO
862.3620	Methadone test system	DJR
862.3610	Methamphetamine test system	DJC
862.3650	Opiate test system	DJG
862.3650	Opiate test system (Oxycodone)	DJG
	Phencyclidine	LCM
862.3870	Cannabinoid test system	LDJ

Predicate Device: At Home Drug Test Models 9308T and 9308Z

Intended Use:
The QuickScreen Drug Screening Test System is a rapid, qualitative immunoassay for the detection of amphetamine, barbiturates, benzodiazepines, cocaine, methadone,

methamphetamines, opiates, oxycodone, phencyclidine and THC or their metabolites in urine. This assay is intended to assist in the prevention of drug abuse. The cut-off concentrations of this test are as follows:

Analyte	Calibrator	Cutoff
Amphetamine	d amphetamine	1000 ng/ml
Cocaine	benzoylecgonine	150 ng/ml
Methamphetamine	d methamphetamine	500 ng/ml
Opiates	morphine	300 ng/ml
PCP	phencyclidine	25 ng/ml
Barbiturates	Secobarbital	200 ng/ml
Benzodiazepines	Oxazepam	200 ng/ml
Methadone	Methadone	300 ng/ml
Oxycodone	Oxycodone	100 ng/ml
THC	Cannabinoids	50 ng/ml

The QuickScreen Drug Screening Test System is for in-vitro diagnostic use and is intended for use in point-of-care settings.

Configurations of the QuickScreen Drug Screening Test System may consist of any combination of the above listed and previously cleared drug. Refer to specific product labeling for the combination of drug tests included on that test device.

Similarities and differences to predicate device:

The QuickScreen Drug Screening Test system, like many commercially available drug screening test kits, qualitatively measures the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Phamatech QuickScreen At Home Drug Test and the Phamatech QuickScreen Pro Multi Drug Screening Test. All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / target drug / antibody / complexes.

	At Home Test **Model 9308T & 9308Z**	QuickScreen™ Drug Screening Test System
510(k) #	K070009	K103295
Format	Integrated Cup/ Dip Card	Integrated Cup/Dip Card/Cassette
Use	In vitro diagnostic	In vitro diagnostic

Intended Use	Detection of: cocaine (benzoylecgonine) THC, opiates, amphetamine, methamphetamine, Benzodiazepines, barbiturates, methadone PCP OXY	Detection of: cocaine (benzoylecgonine) THC, opiates, amphetamine, methamphetamine, Benzodiazepines, barbiturates, methadone PCP OXY
Specimen	Urine	Urine
Methodology	Lateral flow Immunoassay	Lateral flow Immunoassay
Qualitative	YES	YES
Antibodies	Monoclonal / Polyclonal	Monoclonal / Polyclonal
Analyte's detected	10	10
Cutoffs (ng/ml)	**Cocaine: 300** THC: 50 AMP 1000 Opiates: 300 PCP: 25 MET: 500 BZD: 200 Barb: 200 MTD: 300 OXY 100	**Cocaine: 150** THC: 50 AMP 1000 Opiates: 300 PCP: 25 MET: 500 BZD: 200 Barb: 200 MTD: 300 OXY 100
Incubation	10 minutes	10 minutes
Control Features	Control Line Test Expired Indicator	Control Line Test Expired Indicator
End User	Home (OTC) Use	Point of Care Use

The performance characteristics of the QuickScreen Drug Screening Test system for common analytes are exactly the same. They have not been altered by the change in cutoff concentration of the cocaine test.

See k070009 for amphetamine, barbiturates, benzodiazepines, cocaine, methadone, methamphetamines, opiates, oxycodone, phencyclidine and THC or their metabolites. Performance studies were conducted for the change to a 150ng/ml cutoff concentration for cocaine.

The following laboratory performance studies were performed to determine substantial equivalence of the QuickScreen Drug Screening Test system to the predicate:

Performance: The performance characteristics of the QuickScreen Drug Screening Test system for common analytes was evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the QuickScreen Drug Screening Test system to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of the stated target drugs in urine.

Method Comparison – The performance of the QuickScreen™ devices was evaluated with 3 operators who are typical operators at this site. Operators tested 80 unaltered clinical urine samples. The samples were blinded and sufficiently randomized and compared to GC/MS results. The results are presented below:

COC 150		**Negative <50% of cutoff**	**Near Cutoff 50% to cutoff**	**Near Cutoff Positive to + 50 %**	**High Positive >50% of cutoff**	**% Agreement**
Dipcard	+		1	17	28	98.75
	-	20	19			100
Cassette	+		1	16	28	98.75
	-	20	19			100
Cup	+		1	16	28	98.75
	-	20	19			100
Multi-dip	+		2	16	28	97.5
	-	24	18			100

Cutoff Value (ng/ml)	Phamatech COC150 (Pos/Neg)	Drug/Metabolite GC/MS value (ng/ml)
150	Positive (card)	147.1 148.16
150	Positive (cup)	144
150	Positive (card)	144

Performance of the QuickScreen Drug Screening Test system around cutoff for cocaine (benzoylecgonine) was evaluated by testing standard drug solutions diluted in drug free urine at 3 sites by 3 technicians in card, cup and cassette formats for a period of 20 days. The results are summarized below:

Sensitivity / Precision at 4 sites:

CONCENTRATION (ng/ml)	Multi Card		Cup		Cassette	
Negative	40	0	40	0	40	0
-75%	80	0	80	0	80	0
-50%	80	0	80	0	80	0

-25%	80	0	80	0	80	0
Cutoff	12	68	21	59	15	65
125%	0	80	0	80	0	80
150%	0	80	0	80	0	80
175%	0	80	0	80	0	80
200%	0	80	0	80	0	80

Other technical performance tests include:

Assay Interference – Negative base
Assay Interference – Positive base
Lot to Lot Consistency
Prozone Response
Effect of Sample pH
Test Strip Dip Time Flex
Read Time Flex
Sample Temperature Flex
Specific Gravity Effects
Format Equivalency

Conclusion: For the reasons mentioned above, it may be concluded that Phamatech's QuickScreen Drug Test system is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the point of care technician.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 0 1 2012

PHAMATECH INC
c/o Carl Mongiovi
10151 Barnes Canyon Rd
San Diego, CA 92121

Re: k103295
Trade Name: Quickscreen Cocaine 150 Test, Quickscreen Multi Drug Screening Test, Quickscreen Drug Cup Test
Regulation Number: 21 CFR §862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Codes: DIO
Dated: September 14, 2011
Received: January 18, 2012

Dear Mr. Mongiovi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K 103295 .

Device Name: QuickScreen™ Cocaine 150 Test Model 9050T Dip Card and 9051 Cassette

Indications for Use:

The QuickScreen Cocaine 150 Test is an in-vitro diagnostic test for the detection/presence of cocaine (benzoylecgonine) in urine. The cut-off concentration is 150 ng/ml. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. This test is intended for point-of-care testing.

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Prescription Use: ____X____ AND/OR Over the Counter Use: _____
(Part 21 CFR 801 Subpart D (21 CFR 807 Subpart C)

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Concurrence of the CDRH Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K103295

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K 103295 .

Device Name: QuickScreen™ Multi Drug Screening Test Model 9339T Dip Card

Indications for Use:

An invitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, Barbiturates, benzodiazepines, methadone , oxycodone and THC in urine. Tests for barbiturates cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. This test is intended for point-of-care testing.

Analyte	Calibrator	Cutoff
Amphetamine	d amphetamine	1000 ng/ml
Cocaine	benzoylecgonine	150 ng/ml
Methamphetamine	d methamphetamine	500 ng/ml
Opiates	morphine	300 ng/ml
PCP	phencyclidine	25 ng/ml
Barbiturates	Secobarbital	200 ng/ml
Benzodiazepines	Oxazepam	200 ng/ml
Methadone	Methadone	300 ng/ml
Oxycodone	Oxycodone	100 ng/ml
THC	Cannabinoids	50 ng/ml

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Prescription Use: ____X____ AND/OR Over the Counter Use: _____
(Part 21 CFR 801 Subpart D (21 CFR 807 Subpart C)

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Device Evaluation and Safety

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INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K 103295

Device Name: QuickScreen™ Drug Cup Model 9339Z

Indications for Use:

An invitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, Barbiturates, benzodiazepines, methadone, oxycodone and THC in urine. Tests for barbiturates cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. This test is intended for point-of-care testing.

Analyte	Calibrator	Cutoff
Amphetamine	d amphetamine	1000 ng/ml
Cocaine	benzoylecgonine	150 ng/ml
Methamphetamine	d methamphetamine	500 ng/ml
Opiates	morphine	300 ng/ml
PCP	phencyclidine	25 ng/ml
Barbiturates	Secobarbital	200 ng/ml
Benzodiazepines	Oxazepam	200 ng/ml
Methadone	Methadone	300 ng/ml
Oxycodone	Oxycodone	100 ng/ml
THC	Cannabinoids	50 ng/ml

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Prescription Use:____X____ AND/OR Over the Counter Use:_____
(Part 21 CFR 801 Subpart D (21 CFR 807 Subpart C)

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